510(k) Summary
for the Medix Biochemica
Actim PROM

JAN 25 2007

1. Applicant/Sponsor

Medix Biochemica
Asematie 13
02700 Kauniainen
Finland

Contact Person: Heli Paloheimo
Telephone: 358 9 547 680

Date Prepared: January 5, 2007

2. Device Name

Proprietary Name:	Actim PROM and Actim PROM Controls
Common/Usual Name:	Rupture Of Fetal Membranes (ROM) Rapid Diagnostic Test
Classification Name:	Urinary pH (Nonquantitative) Test System and Quality Control Material (Assayed and Unassayed)

3. Predicate Device

AmniSure ROM (Rupture Of [fetal] Membranes) Test
N-Dia, Inc.
K030849

4. Device Description

The Actim PROM is a rapid test for detection of premature rupture of fetal membranes. The test principle is lateral flow immunochromatography. Actim PROM is available in packages of 3, 10 and 20 tests. Each individual test pack contains a sterile polyester swab, specimen extraction solution and a dipstick. The dipstick is packed in a foil pouch with desiccant.

The Actim PROM Controls contain one vial each of negative, low positive and high positive controls, and reconstitution solution.

5. Intended Use

The Actim PROM test is a visually interpreted, qualitative immunochromatographic rapid test for the detection of amniotic fluid in cervicovaginal secretions during pregnancy. Actim PROM test detects IGFBP-1, which is a major protein in amniotic fluid and a marker of the presence of amniotic fluid in a cervicovaginal sample. The test is intended for professional use to help diagnose the rupture of fetal membranes (ROM) in pregnant women at >34 weeks gestation when patients report signs, symptoms or complaints suggestive of ROM or if such signs are otherwise observed.

The Actim PROM Controls are intended for use as external controls with the Actim PROM test. The controls may also be used to demonstrate negative results and weak and strong positive results.

6. Technological Characteristics and Substantial Equivalence

The Actim PROM and the predicate device cited above are both qualitative, lateral flow immunochromatographic assays intended to aid in detecting rupture of fetal membranes in pregnant women. Detection of results is by visual inspection for both tests. The analytes detected by both the Actim PROM and AmniSure tests are thought to be very similar. The specimen collection and extraction, test procedure, and reading and interpretation of results is similar between the two devices. Both devices are intended for use in point-of-care and clinical laboratory settings.

The differences between the Actim PROM and the predicate device do not impact the safety or effectiveness of the proposed Actim PROM products for their intended uses.

7. Performance Testing

A series of nonclinical studies was conducted to assess the performance of the Actim PROM and Actim PROM Controls. These studies evaluated method comparison, repeatability, reproducibility, analytical sensitivity, analytical specificity and interfering substances. The results of all studies demonstrated that the Actim PROM and Actim PROM Controls performed according to their specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Cynthia Sinclair
Medix Biochemica
49 Plain Street
North Attelboro, MA 02760

JAN 25 2007

Re: k061886
Trade/Device Name: Actim PROM
Regulation Number: 21 CFR§862.1550
Regulation Name: Urinary pH (nonquantitative) test system.
Regulatory Class: Class I
Product Code: OAM, JJX
Dated: November 29, 2006
Received: November 30, 2006

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061886

Device Name: Actim PROM

Indications for Use:

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Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

...n Sign-Off

...ce of In Vitro Diagnostic Device
...luation and Safety

K061886